

Translation

PATENT COOPERATION TREATY

PCT/JP2003/010562



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference ONF-4650PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2003/010562	International filing date (day/month/year) 21 August 2003 (21.08.2003)	Priority date (day/month/year) 22 August 2002 (22.08.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/196, 31/5575, 9/48, 47/14, 47/38, A61P 1/00, 13/12, 29/00, 43/00		
Applicant ONO PHARMACEUTICAL CO., LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
  - a. ☐ (sent to the applicant and to the International Bureau) a total of \_\_\_\_\_ sheets, as follows:
    - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - b. ☐ (sent to the International Bureau only) a total of \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> Box No. I  | Basis of the report   |
| <input type="checkbox"/> Box No. II            | Priority  |
| <input type="checkbox"/> Box No. III           | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/> Box No. IV            | Lack of unity of invention  |
| <input checked="" type="checkbox"/> Box No. V  | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> Box No. VI | Certain documents cited   |
| <input type="checkbox"/> Box No. VII           | Certain defects in the international application  |
| <input type="checkbox"/> Box No. VIII          | Certain observations on the international application   |

Date of submission of the demand 06 February 2004 (06.02.2004)	Date of completion of this report 27 May 2004 (27.05.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/010562

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the claims:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/JP 03/10562

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	1-33	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-33	NO
Industrial applicability (IA)	Claims	1-33	YES
	Claims		NO

### 2. Citations and explanations

The inventions set forth in claims 1-33 are not disclosed in any of the documents cited in the international search report, and are novel. In particular, the fact that ornoprostil alleviates the adverse effects of diclofenac is not disclosed even in document 1, which is considered to be the most relevant of the prior art documents.

The inventions set forth in claims 1-33 do not involve an inventive step in the light of document 1, cited in the international search report. Document 1 discloses the fact that ornoprostil alleviates gastric disturbance induced by NSAIDs (non-steroid anti-inflammatory drugs). Document 1 does not mention that ornoprostil alleviates the adverse effects of diclofenac; however, given that diclofenac is recognized within this technical field to be a typical NSAID, document 1 can be considered to suggest that ornoprostil alleviates the adverse effects of diclofenac. Therefore, a person skilled in the art could easily conceive of adopting this constitution.

Document 1: J. J. Ares et al., "Gastroprotective agents for the prevention of NSAID-induced

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

International application No.

PCT/JP 03/10562

gastropathy", Current Pharmaceutical Design,  
1998, Vol. 4, No. 1, pp. 17-36; especially  
page 20, left column

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/010562

## Box No. VI Certain documents cited

## 1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 02/066030 A1 [EX]	29 August 2002 (29.08.2002)	20 February 2002 (20.02.2002)	22 February 2001 (22.02.2001)

## 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)